

REMARKS

Applicants respectfully request reconsideration and further examination of the present application.

I. Amendments to the Claims

With this Amendment B, claims 36 and 37 have been amended, while claims 48 to 79 have been added. Accordingly, claims 36 to 79 are now pending.

Claim 36 has been amended to now specifically call for a compound having cytoprotective activity which has one or more unsaturated bonds in conjugation with the A-ring of the structure shown, and the noted stereochemistry at carbons 8, 9, 13 and 14, when one or more of these carbons is not part of a noted unsaturated bond. Additionally, this claim has been amended to provide for multiple R_z substituents on the D-ring of the compound. Support for these amendment may be found in original claim 36, as well as in the specification, for example, on page 14, lines 14-26.

Claim 37 has been amended for purposes of clarification, in view of the amendment to claim 36. More specifically, claim 37 has been amended to indicate that t is 1. Support for this amendment may be found in original claim 37, as well as in the specification, for example, on page 14, lines 14-26.

Support for new claims 48-79 may be found in original claim 36, as well as in the specification, for example, on page 14, lines 14-26 and page 17, line 17.

II. Election of Species

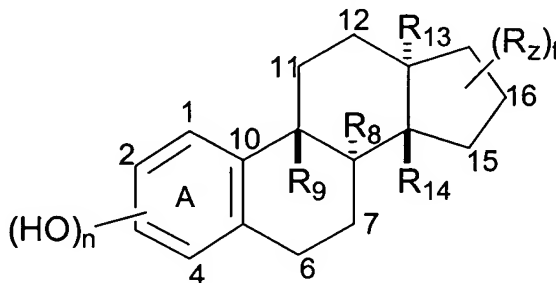
The species previously elected reads on at least claims 36, 39-47 and 53-55.

III. Rejections under 35 U.S.C. §102

A. 35 U.S.C. §102(b)

Reconsideration is respectfully requested of the rejection of claims 36, 37, 39-44 and 46, as being anticipated by one or more of the following references: Romer I (Steroids, 1997, pp. 688-94), GB 1 298 587, Tietze (Steroids, 1994), Simpkins (WO 97/03661), Bonfils (5,679,668), Romer II (Steroids, 1997, pp. 304-10), Lunn (Tetrahedron, 1968), and Gemmill (5,552,395).

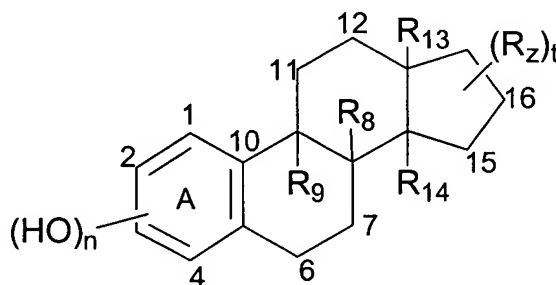
As amended, claim 36, from which claims 37, 39-44 and 46 depend, is directed to a cytoprotective compound having an aromatic A-ring and one or more unsaturated bonds in the B- or C-rings which are in conjugation therewith. Additionally, as indicated by the structure presented below, when not part of one these unsaturated bonds, the compound has up to four carbon atoms (i.e., carbons 8, 9, 13 and 14) which have a specific stereochemical configuration (as indicated in the structure, below):



None of the cited references disclose a compound which satisfies each of the noted requirements. Specifically, none of the cited references disclose a compound which has an unsaturated carbon-carbon bond that is in conjugation with the A-ring (i.e., an unsaturated bond between carbons 6 and 7, 8 and 9, or 9 and 11), and which also has the noted stereochemical configuration at carbons 8 and 9 (when not part of an unsaturated bond), 13 and 14.

In view of the foregoing, claim 36 is submitted as novel over the cited references. In as much as claims 37, 39-44 and 46, as well as new claims 48-56, depend directly or indirectly from claim 36, these claims are submitted as novel over the cited references for at least the same reasons as those noted with respect to claim 36. Although these claims include additional novel features, these features will not be addressed at this time in the interests of brevity.

With respect to the newly submitted claim 57, from which claims 58-68 depend, it is to be noted that, as indicated by the structure presented below, claim 57 is directed to a cytoprotective compound having an aromatic A-ring, and additionally (i) one or more unsaturated bonds in conjugation with the aromatic A ring between carbons 6 and 7, 8 and 9, or 9 and 11 (in which event one or both of R^8 and R^9 will be absent), (ii) a stereochemical configuration of, when present, 8α , 9β , 13α and 14β , or (iii) both (i) and (ii).

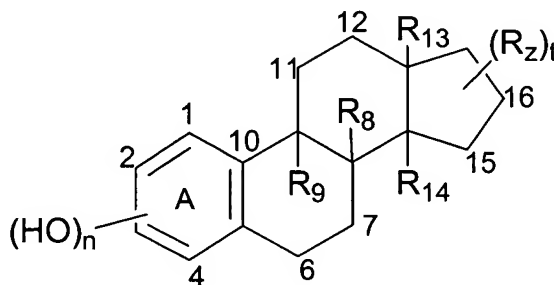


The claimed compound is further characterized by the requirement that the hydroxy group or groups on the A-ring be present at a position other than carbon 3; that is, the A-ring may have from 1 to 3 hydroxy groups which may be present on carbons 1, 2 and/or 4, carbon 3 thus being unsubstituted.

In contrast to claim 57, none of the cited references disclose a compound which satisfies each of the noted requirements. Specifically, none of the cited references disclose a compound which has an unsaturated carbon-carbon bond in conjugation with

the A-ring, the noted stereochemical configuration, or both, and which has a hydroxy-substituent at a position on the A-ring other than the carbon 3 position.

With respect to the newly submitted claim 69, from which claims 70-79 depend, it is to be noted that, as indicated by the structure presented below, claim 69 is directed to a cytoprotective compound having an aromatic A-ring, and additionally (i) one or more unsaturated bonds in conjugation with the aromatic A ring between carbons 6 and 7, 8 and 9, or 9 and 11 (in which event one or both of R^8 and R^9 will be absent), (ii) a stereochemical configuration of, when present, 8α , 9β , 13α and 14β , or (iii) both (i) and (ii).



The claimed compound is further characterized by the requirement that the substituent or substituents defined by R_z on the D-ring be present at a position other than carbon 17; that is, the D-ring may have 1 or 2 R_z substituents which may be present on carbons 15 and/or 16, carbon 17 thus only being substituted with hydrogen atoms.

In contrast to claim 69, none of the cited references disclose a compound which satisfies each of the noted requirements. Specifically, none of the cited references disclose a compound which has an unsaturated carbon-carbon bond in conjugation with the A-ring, the noted stereochemical configuration, or both, and which has a substituent, as defined by R_z , at a position on the D-ring other than the carbon 17 position; that is, none of the cited references disclose compounds having an unsaturated carbon-carbon bond in conjugation with the A-ring, the noted

stereochemical configuration, or both, and only hydrogen substituents at the carbon 17 position (carbon 17 thus being unsubstituted).

In view of the fact that none of the cited references disclose a compound which falls within the limitations of claims 57 or 69, or the claims depending therefrom, these claims are submitted as novel over the cited references as well. Although the dependent claims include additional novel features, these features will not be addressed at this time in the interests of brevity.

B. 35 U.S.C. §102(a)

In response to the rejection of claims 36 and 39-47 as being anticipated by the published German Patent Application DE 199 17 930, enclosed with this Amendment B is the declaration of Dr. Douglas F. Covey which, pursuant to 37 C.F.R. §1.131, provides evidence that the date of invention, for the invention as claimed herein, is prior to the publication date of this reference (i.e., prior to October 19, 2000). Accordingly, reconsideration of this rejection is respectfully requested.

Additionally, Applicant respectfully submits that this reference fails to disclose a specific compound which satisfies each of the requirements of claims 57 or 69, as well as the claims depending therefrom.

IV. Rejection under 35 U.S.C. §112, Second Paragraph

Reconsideration is respectfully requested of the rejection of claims 36, 37 and 39-44 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention,

the Office having rejected these claims due to the indefinite nature of the term "amido," "heterocycloalkyl" and heterocycloalkenyl," as used in the definition of R_z .¹

With respect to the term "amido," Applicant respectfully submits that this is a common term of art, and thus is a term one of ordinary skill in the art would easily recognize, which refers to an amide substituent attached to the structure. More specifically, Applicant respectfully submits one of ordinary skilled in the art would recognize this refers generally to a substituent characterized as "-C(=O)NRR," wherein the carbonyl carbon therein is bound to the structure, and each R that is bound to the nitrogen atom is a substituent that would also be recognized by one of ordinary skilled in the art.

With respect to the terms "heterocycloalkyl" and heterocycloalkenyl," Applicant respectfully submits these are also common terms of art, and thus are terms that one of ordinary skill in the art would easily recognize, which refer to cyclic alkyl substituents (i.e., "cycloalkyl") and cyclic alkyl substituents having a carbon-carbon double bond therein (i.e., "cycloalkenyl"), respectively, wherein a carbon atom in these cyclic substituents has been replaced by a heteroatom (such as, for example, oxygen or nitrogen).

Given that the above-noted terms are terms of art, and thus are terms that one of ordinary skill in the art would recognize, Applicant respectfully submits these terms need not be defined in the specification. Furthermore, Applicant submits that these terms are not indefinite. Accordingly, reconsideration of this rejection is respectfully requested.

¹ It is to be noted that claim 36, as amended, no longer includes a reference to "amido" in the list of potential substituents encompassed by R^{13} . Additionally, it is to be noted that new claims 57 and 69 also do not include "amido" as a potential option for R^{13} .

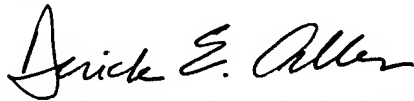
V. Allowable Subject Matter

Applicant respectfully acknowledges the finding that claim 38 would be allowable if rewritten in independent form, including all the limitations of the base claim and any intervening claims.

CONCLUSION

* Applicants enclose a check in the amount of \$109.00 to cover the one-month extension of time (\$55.00) and additional claims fee (\$54.00). The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 19-1345.

Respectfully submitted,



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* Enclosures